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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/598,267

06/17/2008

Lawrence Solomon

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31673

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07/11/2011

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EXAMINER

CHANNAVAJJALA, LAKSHMI SARADA

ART UNIT

PAPER NUMBER

1611

MAIL DATE

DELIVERY MODE

07/11/2011

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/598,267	Applicant(s) SOLOMON ET AL.
	Examiner LAKSHMI CHANNAVAJJALA	Art Unit 1611

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 30 April 2011.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| <p>1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)</p> <p>2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)</p> <p>3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
 Paper No(s)/Mail Date _____.</p> | <p>4) <input type="checkbox"/> Interview Summary (PTO-413)
 Paper No(s)/Mail Date. _____.</p> <p>5) <input type="checkbox"/> Notice of Informal Patent Application</p> <p>6) <input type="checkbox"/> Other: _____.</p> |
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DETAILED ACTION

Receipt of amendment, terminal disclaimers and response all dated 4/30/11 is acknowledged.

Claims 1-19 are pending in the instant application.

In response to the amendment, the following rejection of record has been withdrawn:

Claims 1-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 2002/0132850 to Bartholomaeus et al (Bartholomaeus), and further in view of US 5756124 to Patel et al and 6,375,956 to Hermelin et al.

Terminal Disclaimer

1. The terminal disclaimer filed on 4/30/11 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of 7318935; 7329418; 7622137; 7713547 and 7838031 has been reviewed and is accepted. The terminal disclaimer has been recorded.

In response to the amendment, the following rejection of record has been withdrawn:

Claims 1-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 2002/0132850 to Bartholomaeus et al (Bartholomaeus), and further in view of US 5756124 to Patel et al and 6,375,956 to Hermelin et al.

The following new rejection is applied to the pending claims:

Claim Rejections - 35 USC § 103

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

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3. Claims 1-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 2002/0132850 to Bartholomaeus et al (Bartholomaeus), in view of US 4,215,104 to Ullmann et al and Pharmaceutical industry info (2003), and further in view of US 5,756,124 to Patel et al and 6,375,956 to Hermelin et al.

4. Bartholomaeus teaches a multilayered tablet (three or five or up to seven layers) containing two different actives (tramadol and diclofenac), each in a separate layer and separating layer between the active layers. This separating layer is clearly provided to ensure complete separation of the two active layers and to minimize interaction between the two different actives or the compositions comprising those actives, which may be pharmaceutically incompatible with one another. Bartholomaeus teaches incorporating an immediate release substance, for an initial dose of pain relieving active agent (0013). Bartholomaeus teaches that the tablet may contain up to five or seven layers (0009). Applicants state that the inactive segment of the instant invention provides an advantage of separating the actives (page 10). In this regard, Bartholomaeus teaches separation of the active agents by the addition of an inactive barrier layer and thus meets instant invention. For claimed score mark, Bartholomaeus further teaches that the tablet provides at least one score mark that enables the dose being administered into two halves, so as to match to the individual requirements of the patient (0030-0031). Thus, it would have been obvious for one of ordinary skill in the art at the time of the instant invention to include a score mark in the middle segment of Bartholomaeus so as to achieve two equal halves of a tablet containing different active agents. Bartholomaeus does not state if the score is vertically oriented.

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5. Ullmann teaches multi-fractionable tablets configured in a unitary dosage form, where the tablets can be severed into several dosage forms, with score markings positioned variably for accurate breaking of the tablet. Fig. 5 of Ullmann shows tablets with scores on the vertical axis and figs 1-2, 4, 6 etc., shows tablets with scores on the horizontal axis.

6. Further, Bartholomaeus suggests that the score may be placed such that the tablet may be halved. Accordingly, choosing the size and orientation of the score so as to break the tablet exactly into halves would have been within the scope of a skilled artisan.

7. Bartholomaeus fails to teach the claimed indicia and also lacks the color in the inner segment. However, the teachings of Patel and Hermelin are relied upon for the same. Patel teaches breakable multiscored tablets wherein the tablets can be divided in to plurality of predetermined dosages and the dosages are separated by score marks.

8. Figs. 1 and 2 of Patel show the score marks as well as indicia on the tablets which indicate the dosage of the tablet fraction.

9. Hermelin teaches strip pack containing drugs that require complex dosage regimen for simultaneous administration of drugs (abstract) based on individual requirement. The blister packs of Hermelin contains plurality of predetermined dosages of drugs, wherein a day indicia is provided with each dosage (col. 6), for dispensing combinations of drugs (col. 8). Hermelin also suggests color coding the different drugs such that the drugs can be taken at different times of the day (col. 16, l 35+).

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10. Therefore, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention was made to employ not only score (of Bartholomaeus) for breaking the tablet accurately, but also include indicia on the tablets for instance the type of drug included or color code so as to indicate the inert or drug containing segments in the tablet of Bartholomaeus such that the tablet can be broken for appropriate drug based on the information printed or the color code, from either top or bottom segment of the tablet, without losing the active agent during breakage and dispensing. Further, a skilled artisan would have recognized that employing more than one score for easy breakage of the tablet as needed is routine in the art from the teachings of Patel.

11. With respect to the new limitation i.e., "tablet height greater than width....while it is in the die in which it is fully compressed", the above references do not teach the limitation. However, applicants describe in the instant specification that taller than wide tablets can be made on a tablet press such as KORSCH TRP900 (page 30, lines 1-21). The attached document of Pharmaceutical Industry info also shows that KORSCH TRP 700/900 teaches 3-5 layer tablets that are taller than wider (700/900-3s/5s on page 5) as well as square or circular tablets. Thus, by applicants' own admission, it is conventional to prepare multilayered tablets that are taller than wider and it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to prepare the tablets of Bartholomaeus containing two active agent segments with an inactive segment containing a score mark and also prepare tablets that are taller than wider while the tablet is still in the die because a skilled artisan would have readily

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recognized the various design choices in preparing tablets from the teachings of Pharmaceutical Industry Info including the claimed multi-layered taller than wider tablets.

Response to Arguments

12. Applicant's arguments filed 4/30/11 have been fully considered but they are not persuasive.

13. Applicants' arguments with respect to the previous rejection are moot in light of the withdrawn rejection and also in light of the newly added references. The newly added Ullmann reference addresses the applicants' arguments regarding the score being present in a non-vertical fashion. Instant claims do not include any specific size for the inactive layer and hence the argument that Bartholomaeus teaches as thin layer as possible (including the evidence of Liebermann and Lachman provided by applicants) has not been found persuasive. Applicants merely argue that instant tablets offer unique advantages without actually claiming any limitations that provide the advantages. The argument "a relatively thick segment" is not persuasive because the term is relative and is not clear what actual thickness is. The new reference also provides taller-than-wide tablets (Pharma Info) claimed.

Conclusion

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAKSHMI CHANNAVAJJALA whose telephone number is (571)272-0591. The examiner can normally be reached on 9.00 AM -5.30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila G. Landau can be reached on 571-272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lakshmi S Channavajjala/
Primary Examiner, Art Unit 1611